REMARKS/ARGUMENTS

Claims 1-116 are currently pending. No claims are amended. These claims are believed to place the application in condition for allowance.

The Office Action required three separate restriction requirements to an allegedly distinct species. Applicants provisionally elect a method of (1) treating (3) myocardial ischemia with (2) microgranules **with traverse**, for the reasons discussed *infra*.

The Office Action alleges:

> 1. This application contains claims directed to the following patentably distinct species:
>
> The instant application comprising a plurality of disclosed patentably distinct processes:
>
> a) Treating a myocardial ischemia and angina.
>
> b) Preventing a myocardial ischemia and angina.

Applicants hereby provisionally elect a method of treating myocardial ischemia and angina, which is covered by claims 1-116, **with traverse**.

Applicants respectfully urge that the Restriction Requirement is improper, as it does not establish that searching all the species would constitute an undue burden on the Office. Accordingly, Applicants submit that the Restriction Requirement is improper and should be withdrawn or at least modified.

According to the MPEP, "[a] requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if the restriction is not required." MPEP § 808.01(a) (emphasis added). In establishing that an "undue burden" would exist for co-examination of the species, the Office must show that the examination of the species would involve substantially different prior art searches, making the co-examination burdensome. To show undue burden resulting from searching difficulties, the Office must show that the restricted species have a different classification, acquired a separate status in the art, or that searching would require different fields of search. *See* MPEP § 808.02.

Applicants submit that it would not constitute an undue burden on the Office to examine a method of treating myocardial ischemia and angina with a method of preventing myocardial ischemia and angina. The species, while patentably distinct from each other, are related in that the claimed methods involve the administration of the same formulations and the same disorders/diseases/symptoms are being targeted. Accordingly, it would not constitute an undue

burden to examine a method of treating myocardial ischemia and angina with a method of preventing myocardial ischemia and angina.

The Office Action further alleges:

> 2. This application contains claims directed to the following patentably distinct species:
>
> The form comprising of preparation in the form of
>
> a) Capsule.
> b) Tablet.
> c) Microgranules.
> d) Microgranules in capsule.
> e) Microgranules in tablet.

Applicants hereby provisionally elect microgranules, which are covered by claims 1-6, 9-116, **with traverse**.

As discussed *supra*, "[a] requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if the restriction is not required." MPEP § 808.01(a) (emphasis added). Applicants respectfully submit that the Restriction Requirement is improper, as it does not establish that searching all the species would constitute an undue burden on the Office.

Applicants submit that it would not constitute an undue burden on the Office to examine a method of treating and preventing myocardial ischemia with any of the dosage forms listed in the Office Action because regardless of the dosage form, the methods provide a method of administering the same claimed amount of Diltiazem, administration that targets the same disorders/diseases/symptoms and administration that achieves the same claimed pharmacokinetic properties.

Furthermore, it is submitted that it would not represent an undue burden on the Office to search at least (c), (d), and (e) together because the species (c) encompasses the species (d) and (e). A complete search of microgranules would include a full search of tablets and/or capsules comprising microgranules. Accordingly, the Office Action fails to establish an undue burden in searching species (c)-(e).

The Office Action finally alleges:

> 3. This application contains claims directed to the following patentably distinct species:
>
> The disease comprising of
>
> a) Myocardial Ischemia.
> b) Angina.

Applicants hereby provisionally elect myocardial ischemia, which are covered by claims 1-116, **with traverse**.

As discussed *supra*, "[a] requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if the restriction is not required." MPEP § 808.01(a) (emphasis added). Applicants respectfully submit that the Restriction Requirement is improper, as it does not establish that searching all the species would constitute an undue burden on the Office.

Applicants submit that it would not constitute an undue burden on the Office to examine a method of treating and preventing myocardial ischemia with a method of treating and preventing angina because, *inter alia*, angina is known to be a symptom of myocardial ischemia. Accordingly, a search for a method of treating and preventing myocardial ischemia would include a search for a method of treating and preventing angina. As such, Applicants respectfully submit that it would not be an undue burden on the Office to search a method of treating and preventing myocardial ischemia with a method of treating and preventing angina.

In view of the above remarks, it is respectfully requested that the Restriction Requirement be withdrawn and that all species be prosecuted together.

CONCLUSION

In view of the foregoing, early notification of a favorable consideration is respectfully requested.

Because this response is filed within one month of the mailing date of the Restriction Requirement, Applicants believe that no fees are due. In the event any variance exists between the amount authorized to be charged to the Deposit Account and the Patent Office charges, please charge or credit any difference to the undersigned's Deposit Account No. **50-0206**.

Respectfully submitted,

Dated: 11/01/06 By: _____

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